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APPLICATION NUMBER 12/18/98	FILING DATE 12/18/98	FIRST NAMED APPLICANT LIPARI	ATTY. DOCKET NO. J 6439.US.01
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HM12/0706

EXAMINER

ART UNIT PAPER NUMBER

1615

DATE MAILED: 07/06/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 2-16-01

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-8, 12-17 & 19-20 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-8, 12-17 & 19-20 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 14
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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DETAILED ACTION

The change of address dated 1-8-01, the request for the extension of time, filing under 1.114, formal drawings, the preliminary amendment and the terminal disclaimer dated 2-16-01 and the associate power of attorney dated 3-23-01 are acknowledged.

Claims included in the prosecution are 1-8, 12-17, and 19-20.

Claim Rejections - 35 U.S.C. § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 1-8, 12-17 and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The nature of the formulation in claim 1 is unclear. Claim 1 does not recite the presence of any water, yet the dependent claim recites the presence of a emulsifier.

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Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-8, 12-17 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Lacy (5,645,856).

Lacy discloses capsules containing emulsions of fenofibrate. The emulsions contain a triglyceride, propylene glycol fatty acid esters, polyglycerol esters of fatty acids and a cosolvent; the composition further contains Capric/caprylic triglycerides such as Miglycol and Captex (note columns 4 and 5 and Examples 6 and 7).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant while recognizing that medium chain triglycerides are preferred embodiment in Lacy, argues that in Lacy the these glycerides are part of a carrier which also includes a surfactant. The rationale for this argument is not clear to the examiner. First of all, instant claim does not exclude the surfactant. Secondly, instant dependent claims clearly recite the addition of surfactants and emulsifiers. Applicant argues that the lipid regulating agents of the cited reference are only disclosed in a formulation A in Example 6 and that there is no specific examples of lipid-regulating agents in medium chain glycerol esters of fatty acids. This argument is not found to be persuasive for the

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following reasons. Lacy's example 6 teaches a reasonable number of active agents (just two; fenofibrate and progesterone) in his preferred embodiment of carriers and one of which is a medium chain glyceride (formulation B showing progesterone as the active agent). Thus, reference still meets the requirements of a 102 rejection. Secondly, instant claim 1 recites generic 'lipid regulating agent and 'structured lipid' and what is taught in the reference are compounds which affect lipolysis (lipid regulating) and thus, Lacy's formulations also meet the requirements of instant claims in another way. Besides, one could argue that applicant himself has not provided sufficient examples justifying the broad claims.

5. Claims 1, 4-6, 15, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanchez (5,494,936).

Sanchez teaches 10 percent solution of probucol in a medium chain triglyceride; the composition contains peanut oil and ethanol (note abstract, Table I, col. 8, lines 11-13 and claims).

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 1-8, 12-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanchez and Lacy cited above individually or in combination.

Sanchez or Lacy do not teach all the lipid metabolism regulating agents. It is within the skill of the art to use any lipid regulating agent based on the guidance provided by either Sanchez or Lacy with the expectation of obtaining similar results. One of ordinary skill in the art would be motivated to use fenofibrate instead of probucol in Sanchez because both are directed to the same purpose. It is unclear from Lacy whether the miglycols and Captex used correspond to instant claimed triglycerides. It is deemed to be within the skill of the art to select a proper triglyceride with the expectation of obtaining similar results from the teachings of Lacy; one of ordinary skill in the art would be motivated to use these triglycerides since Sanchez teaches the use of these for the lipid regulating agent probucol. Lacy also does not specifically teach through examples the method of treatment of hyperlipidemia using an effective amount of the fenofibrate. Since the compound is a known lipid metabolism regulating agent, it is deemed obvious to one of ordinary skill in the art to use the formulations for the lipid regulating purposes.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again based on the lack of teachings of instant composition and teaching away. These have been addressed above.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

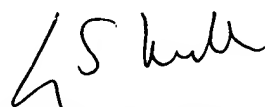
Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is

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more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

July 5, 2001